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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1804]

Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power

Morcellators; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry and FDA staff entitled "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators." FDA is issuing this guidance to recommend the addition of specific safety statements to the product labeling for laparoscopic power morcellators (LPMs). The Agency is making these recommendations in light of scientific information that suggests that the use of these devices contributes to the dissemination and upstaging of an occult uterine malignancy in women undergoing laparoscopic gynecologic surgery for presumed fibroids. FDA believes this effort will promote the safe and effective use of LPMs when used for gynecologic surgeries.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators" to the Office of the Center Director, Guidance and Policy Development, Center for

Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators." This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). FDA believes that immediate implementation of the guidance is needed to assist in addressing a significant public health issue. Although this guidance document is immediately in effect, FDA will consider all comments received and revise the guidance document when appropriate.

As the number of laparoscopic and minimally invasive procedures has increased through the introduction of new surgical technologies and techniques, additional safety information has become available regarding the use of LPMs. Recent discussions within the patient and clinical

communities, as well as the peer-reviewed medical literature, have raised awareness of the risk of spreading unsuspected cancerous tissue beyond the uterus when LPMs are used during gynecologic surgeries intended to treat benign fibroids. Numerous case reports and case series have been published that describe the iatrogenic dissemination, implantation, and subsequent growth of unsuspected neoplastic tissue within the peritoneal cavity following laparoscopic morcellation of uterine tissue believed to contain fibroids based on preoperative diagnosis.

FDA's recent analysis of available information suggested that the risk of an occult uterine sarcoma in a woman undergoing surgical intervention for presumed fibroids is substantially higher than had previously been assumed or reported. FDA's analysis also suggested that patient outcomes, including survival, may be significantly adversely impacted from this upstaging of disease. Patient selection and choice of surgical technique can reduce the risk of spreading cancer. Specifically, the prevalence of unsuspected cancer in women undergoing hysterectomy for fibroids increases with age such that the benefit/risk profile of using LPMs is worse in peri- and post-menopausal women compared to pre-menopausal women. The surgical technique of en bloc tissue removal eliminates the need to perform morcellation, thereby reducing the risk of iatrogenic dissemination and upstaging an occult sarcoma. Importantly, no screening procedure that can reliably detect sarcoma preoperatively has been identified.

FDA considers this new scientific information to represent a significant change to the benefit/risk profile for these devices, prompting the issuance of a Safety Communication on April 17, 2014 (Ref. 1), and convening of the FDA's Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on July 10-11, 2014 (Ref. 2), to further discuss the use and labeling of LPMs during gynecologic surgeries. FDA is issuing this document after

considering the input of the Panel and other stakeholders, including comments made during the Open Public Hearing portion of the Panel meeting.

As a result of the new information and discussions during the public Advisory Committee meeting, FDA recommends that manufacturers of LPMs with a general indication or a specific gynecologic indication prominently include two specific Contraindications and a specific Boxed Warning in their product labeling. FDA believes this may be information that manufacturers should disclose to users under sections 201(n), 502(a), and 502(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n), 352(a) and 352(f)(2)). The issuance of this guidance represents another step in addressing this serious public health issue. In the future, additional safety communications, guidance, or rulemaking may be undertaken to further support the safe and effective use of LPMs.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on product labeling for LPMs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to

download an electronic copy of "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400052 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

In addition, FDA concludes that the labeling statements in the guidance do not constitute a "collection of information" under the Paperwork Reduction Act. Rather, the labeling statements are "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public." (5 CFR 1320.3(c)(2)).

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

VI. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. FDA Center for Devices and Radiological Health, Safety Communications Page, “Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy,” (<http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm393576.htm>).
2. Public meeting in 2014, Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, Federal Register notice, available at <http://www.gpo.gov/fdsys/pkg/FR-2014-06-09/pdf/2014-13290.pdf>.

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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